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10/539,192	06/16/2005	Gordon Feingold	09138.0074	2551
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EXAMINER				
GORDON, BRIAN R				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/539,192

**Applicant(s)**

FEINGOLD ET AL.

**Examiner**

Brian R. Gordon

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 318-357 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 318-357 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 28, 2009 has been entered.

***Response to Arguments***

2. Applicant's arguments filed December 28, 2009 have been fully considered but they are not persuasive.

While applicant has amended the claims in an effort to overcome the previous rejections, the claims are rejected as given herein.

As to the art rejection, applicant asserts that because Tseung discloses that the apparatus **may** include one removable drawer for holding reagents and another removable drawer holding slides that one is prevented from performing the inserting step as claimed. Applicant has only considered (the abstract) a single embodiment of the reference and has not considered the invention as a whole. As stated the apparatus may include one removable drawer, which does not preclude the device from including multiple removable drawers that can accessed independently.

Furthermore it should be noted applicant's arguments are not commensurate in scope with that of the claims. The claims are not directed to the accessibility of drawers.

Tseung discloses that the device includes multiple slide racks 20, each including a plurality of slides. One is not precluded from adding or removing a sample slide(s) while the robotic head processes another slide. (See figures).

Furthermore Tseung discloses "[t]he drawers 68, 70 (reagent and sample drawers) facilitated the exchange of slides 12 while limiting the impact of the exchange on the controlled environment within the processing space 18. In particular, the drawers 68, 70 permit the addition of slides 12, such as slides 12 carrying "stat" tissue specimens, quantities of reagent, and reagent containers 50 to the processing space 18, while limiting the impact of the exchange on the controlled environment within the processing space 18." (column 6, lines 4-28) In other words, the reagents and samples can be inserted and removed without interrupting the processing space.

As to claim 339, applicant asserts Lemme fails to meet the inserting step and disclose the information is received from a laboratory information system.

The device of Lemme includes a plurality of reagent receptors 11, reagent dispensers, and a single dispensing position. It is possible for one to replace one of the reagent dispensers without interrupting the reagent dispenser that is in the dispensing position. (paragraph 0101).

It should be noted that the term "laboratory information system" is not defined by any specific structure. As such, any structure/system (including a conventional computer, server, etc. or host and remote devices disclosed in Lemme) that can

reasonably be seen as being used or located in a lab would meet the limitation as claimed.

As stated in the prior Office Action, it should be recognized that bridges (and other components, such as servers, routers, gateways, etc.) are conventionally well known equipment employed within the configuration of networks to allow for communication between network devices (computers/controllers). Furthermore sending, relaying, and receiving commands, instructions, protocols over computer networks are conventionally known.

The claims do not appear to claim any novel aspects of the use of computer networks. Computer networks are staple components of today's society. It is readily known that WAN and LAN networks are employed for sending various types of data (including encrypted, i.e. internet or intranets) in various environments ranging from private homes, businesses, hospitals (see paragraph 240), laboratories, etc. The use of networking and backup hardware/software is inherent in a network configuration such as that taught by Lemme et al. (see also Showalter, provisional application 60/487,998, prior art submitted by applicant).

It is readily known that computers are equipped to be included within networks. One can go to "network connections" on a PC and view bridge settings and other connections. Furthermore it is known that PCs are equipped with web browsing and troubleshooting/diagnostic software.

It should be noted that applicant has elected not to specify what or who performs the active steps (such as sending, receiving, relaying commands, running diagnostic

tests, troubleshooting, obtaining an estimate, etc.). Therefore this does not preclude the steps from being performed manually or by an automated device.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 318-357 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what elements are involved in establishing a network connection. The connection is between the stainer and what other element(s)? It is further unclear how one performs the steps of sending commands, relaying commands, and receiving responses. It is unclear where commands are sent from. Does an operator send the commands via a key board to the stainer? Are the commands sent from another computer, stainer, or some other device? As such, it is also unclear where or what receives responses and who or what sends responses?

Furthermore it is unclear if wherein clause of "wherein the stainer network in a second computer...." is a considered to be a further step in the process? Is the phrase considered to further clarify the previously recited step of establishing a network connection? Does term "connects" in the phrase have the same or different meaning as establishing a connection? Does it mean a physical connection is made or does it mean a line of communication is established between the elements.

Applicant has amended the claim to include a processing step based upon instructions received. However it is unclear what is the relationship of the claim processing step to the previously recited steps. For example, the previous steps involve sending commands (to somewhere/somebody) and receiving responses to commands (at some place). However, it is unclear what is the relationship of the sent commands and received responses to the processing step. What influence, if any, do the previously recited steps have on the processing step? How are the steps linked to one another?

As to the processing step it is unclear where or who receives the instructions. Are the instructions received by the at least one stainer, second computer, etc.? Are "commands", "instructions", and "responses" considered the same or different?

Furthermore while it is claimed that the processing occurs with the robotic head it is not specified where the processing occurs. While it is stated that the at least one stainer includes a robotic head The claim does not preclude the robotic head from having the ability to move or extend beyond the boundaries of what applicant considers as the stainer. It is conventionally known the robotic arms/heads can have wide ranges of motion. As such, it is foreseeable that the robotic head is not limited to movement and being operated in the at least one stainer.

While applicant has chosen to amend the claim to refer to a stainer network, the claim only requires at least one stainer and at least one computer. Furthermore no structure has been provided as to define what applicant considers as a stainer. As such, any device than can be employed to perform a staining/smearing process can be considered a stainer.

It is unclear what is the difference in "sending commands" and "relaying commands" (claims 321-322, 324, 339). It is unclear if the steps are the same or different. The claims as presently drafted do not preclude a single step such as that of claim 321 from also meeting the sending step of claim 318.

As to claim 321, it is unclear where the database is located. The term "associated with" does not establish a structural relationship between elements. (also applicable to all other claims employing the term, for example claim 326) Furthermore as recited above it is also unclear who or what performs the relaying. (also all other claims including "relaying")

As to claim 323-324, it is unclear if "the commands" recited therein are in reference to the previously recited commands in claim 321 or 318.

As to claim 325 (344 and any other claim directed to software), it is unclear how such software can be used when the claims fail to specify the hardware on which the software is located? Does the stainer include the software? Is the software located on one of the previously mentioned computers?

As to claim 326 (and 345), it unclear who or what performs the respective receiving steps. Furthermore it is unclear how responses to queries to a database can be received when there is no previous step of sending queries to a database. Furthermore it is unclear where the database is located relative to the previously mentioned structure.

As to claim 330, it is unclear what is meant by retrieving diagnostic information. Does this mean results are sent to a specific location (such as computer, display,



printer, etc.)? Does this mean an operator manually records results? Does this mean an operator gathers information for running the tests? Does this mean a computer or other device communicates with some other device/database and electronically collects the information from there?

As to all of the claims, in view of claim 333-334 and 352, it is unclear which steps of the claimed method are intended to involve an operator. It should be noted that a number of recited steps to specify where, how, who, or what performs the steps. As to claim 334, it is unclear if the operator is in the same location is in the same location as the second computer. The claim does not preclude the operator from operating the second computer remotely. Is this interpretation supported by the specification? If not, applicant is not entitled to more than what has been disclosed.

As to claims 335 (and 354), there is no antecedent basis for "other stainers". The claim 318 does not previously establish that any other stainers are present along with the at least one stainer. Furthermore there is no antecedent basis for "the operations". While it has been recited that the method is for performing operations, there is no positive recitation of operations being performed.

As to claims 336-338 and 355-357, it is unclear where, how, who, or what performs the respective steps. Essentially the steps are abstract and can be done mentally. For example, one can observe, estimate, and encrypt by employing mental processes. Such steps are not patentable subject matter.

Claims 339-357 are similar to those of 318-338, applicant should take note that all rejections and comments recited above and below that are applied to 318-338 may also be applicable to claims 339-357.

In addition to the previously applicable rejections, it is unclear where the database recited in claim 339 is located.

As to claim 343, it is unclear how commands and queries can be relayed to a different stainer when claim 339 only requires one stainer. The claim does not positive establish the presence of a different stainer.

Furthermore it should be noted, that claim 343 is conditional as indicated by the term "when". Therefore it is only further limiting of the method if the condition occurs. It is not required that the prior art disclose such, because it is possible that malfunction does not occur.

As to claim 346, it is unclear what responses are being referenced herein when claims 345 and 339 refer to different responses. It is further unclear who, what, or how responses are returned.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 318-357 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention. One skilled in the art would not know how to use the invention as claimed. See 112, 2nd, paragraph rejection.

Applicant has amended the claims, but failed to specify where the amendments are supported within the specification. The examiner fails to locate where the invention as claimed is located and more specifically the amendments. It is hereby requested applicant specify where the claim amendments are supported within the originally filed specification.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
10. Claims 318-357 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tseung et al. US 6,998,270.

Tseung et al. discloses an automated staining system and a reagent container designed for use with the automated staining apparatus. The device includes a control system 28 that includes a data storage unit or medium for storing information, such as staining protocols, and retrieving that stored information on demand. The control system 28 is interfaced by a communication link 31, such as a local area network, so that the autostainer 10 may exchange information with another information storage device 32, such as another laboratory instrument or a remote computer system. For example, the control system 28 may be capable of exporting a staining record containing information such as the staining protocol, reagent information, and the like to the information storage device 32 over the communications link 31. The information storage device 32 would associate the staining record with existing patient information in a patient record database or a laboratory information system and provide, associate, and/or store the

staining record with that information for future report generation. The information storage device may also perform statistical analysis on multiple staining records to, for example, determine compliance with regulatory standards.

The control system 28 is also capable of importing or retrieving information from the information storage device 32 via communications link 31. The imported information may comprise a staining record containing protocol information that the control system 28 can use as a template for staining one or more of the slides 12. The ability to import the staining protocol from device 32 precludes manually inputting the information using touchscreen display 30. The imported information may also include patient information, which may be associated with the staining protocol and/or stored by the control system 28. One use for the associated patient record and staining protocol, whether residing on control system 28 or on information storage device 32, is quality control and quality assurance documentation.

While Tseung does not specify the use of a bridge connector, such hardware and its usage is conventionally known in the art (see Response to Arguments; see Also DeSouza, US 5,245,606). Therefore it would have been obvious to one of ordinary skill in the art to use a bridge to connect multiple computers, networks, and other components to allow for data transmission therebetween.

11. Claims 318-357 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemme et al. US 2002/0110494 A1.

Lemme et al. disclose a method and apparatus for an automated biological reaction system. In the processing of a biological reaction system, there is a need for

consistently placing an amount of fluid on a slide. In order to operate the automated biological reaction system more reliably, the system is designed in modular pieces with higher functions performed by a host device and the execution of the staining operations performed by remote devices. Also, to reliably catalog data which is used by the automated biological reaction system, data is loaded to a memory device, which in turn is used by the operator to update the operator's databases. The generation of the sequence of steps for the automated biological reaction device based on data loaded by the operator, including checks to determine the ability to complete the run. (Abstract).

FIG. 5A, shows a block diagram of the automated biological reaction system 150. The automated biological reaction system 150 is segmented into a host device 32 (server), which includes a typical personal computer, and at least one remote device 166, which includes the automated biological reaction device in FIGS. 2 and 6A. In the preferred embodiment, there are up to eight remote devices 166 which communicate with the host device 32. Each remote device 166 on the network has a unique address so that each remote device 166 may be identified and individually controlled by the host device 32. As described subsequently in FIG. 5B, the automated biological reaction system 150 can support up to eight remote devices 166 due to the 3 bits (values 0-7) dedicated to the addressing of the remote devices 166. A rotary switch is provided on the remote device 166 to allow for the identification and the changing of the 3 bit address for each remote device 166. All host messages include this address in them, as described subsequently in FIG. 5B. However, the number of remote devices 166 can be smaller or larger than eight, depending on the capacity requirements or practical

limitations of the laboratory in terms of space. Moreover, the remote devices 166 may be immunohistochemistry staining modules, another type of instrument that performs a different type of staining, or another type of medical testing device. (paragraph 105).

Communication between the host device 32 and the remote devices 166 is accomplished using a serial RS-485 link, which serves as a network, that supports one host and up to 32 remotes at one time. In the preferred embodiment, addressing of the remote devices 166 allows up to 8 remote devices to communicate with the host at one time. The RS-485 link has at least two pairs of lines for communication, one pair for transmitting and one pair for receiving. The remote devices 166 which are connected to the network "hear" the host messages but do not "hear" other remote messages. In the preferred embodiment, all communications begin with a host message, followed a short time later by a response by a remote device 166 if present. (sending/receiving) If the host device 32 sends a message and there is no remote device 166 to respond to it, the host device 32 times out. In this manner, the communication provides a simple, collision-free link between the host device 32 and the remote devices 166. In an alternative embodiment, the remote devices 166, in addition to communicating with the host device 32, address each other. For example, the remote devices 166 address each other using the unique 3 bit address, sending information about staining runs, which are described subsequently. (paragraph 106).

The user database, which is required by the regulations, contains various tables including the registration, receive and quality control tables for use by the operator. Within each of the registration, receive and quality control tables, there are five different

types of categories: (1) antibodies; (2) reagents; (3) kits; (4) consumables, and (5) control slides. (paragraph 226).

The claims do not appear to claim any novel aspects of the use of computer networks. Computer networks are staple components of today's society. It is readily known that WAN and LAN networks are employed for sending various types of data (including encrypted, i.e. internet or intranets) in various environments ranging from private homes, businesses, hospitals (see paragraph 240), laboratories, etc. The use of networking and backup hardware/software is inherent in a network configuration such as that taught by Lemme et al. (see also Showalter, provisional application 60/487,998, prior art submitted by applicant).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/  
Primary Examiner  
Art Unit 1797